

Record of Proposed Notifiable Low Risk Dealing(s) (NLRDs):

(Regulation 13A(1)(a) - Gene Technology Regulations 2001)

INSTRUCTIONS: Under r.13 of the Gene Technology Regulations 2001 (as amended), the Institutional Biosafety Committee (IBC) must provide a copy of this form to (i) the person or accredited organisation that requested the Committee to assess the proposed dealing; (ii) the project supervisor for the proposed dealing; (iii) with the annual report for Accredited Organisations; and (iv) on request by the Regulator (or her delegates).

Name of Organisation Conducting Dealing	University of Wollongong
Name of IBC	Gene Technology Review Committee (GTRC)
IBC NLRD Identifier (number)	(leave blank)
Date of IBC Approval	(leave blank)
Project Title (should convey the purpose of the dealing)	Examining the impact of the PAC1 gene in female fertility; a knockout mouse experiment
Name(s) of Project Supervisor(s)	Dr John Ross
Scientific Name of Parent Organism	Mus musculus
Vector(s) & Method of Transfer	Knockout mouse lacking the PAC1 gene created by homologous recombination, using embryonic stem cells
Identity & Function of Nucleic Acid & Organism of Origin	Knockout of PAC1 gene, function implicated in female fertility
PC1 NLRD TYPE (a) – (c)*	(a) Gene knockout mouse
PC2 NLRD TYPE (a) – (i) *	
OGTR Certified Facility No.	(Obtain from PC sticker on door of facility)
Do personnel involved in the dealing have appropriate training & experience ? (Yes/No)	Yes
Will the dealing involve the import of GMOs into Australia? (Yes/No)	Yes, mouse model developed in USA.
When was the applicant/ organisation notified of the IBC assessment ? (date)	(leave blank)
When was the Project Supervisor notified of the IBC assessment ? (date)	(leave blank)
Has the IBC assessed the proposed dealing to be an NLRD? (Yes/No)	(leave blank)
IBC Chair (name)	Dr Mark Downton
IBC Chair (signature)	

* Information on the type of NLRD is on the following pages, and is detailed in Parts 1 and 2 in Schedule 3 of the *Gene Technology Regulations 2001* (as amended) available on the OGTR website at www.ogtr.gov.au under the 'IBC & Accredited Orgs' section. An electronic version of this form is also available at the same website location.

Types of Notifiable Low Risk Dealings
Gene Technology Regulations 2001 (as amended)

Schedule 3 Part 1 - Notifiable low risk dealings suitable for physical containment level 1

- (a) a dealing involving a genetically modified laboratory mouse or a genetically modified laboratory rat, unless:
 - (i) an advantage is conferred on the animal by the genetic modification; or
 - (ii) because of the genetic modification, the animal is capable of secreting or producing an infectious agent;
- (b) a dealing involving a host/vector system mentioned in Part 2 of Schedule 2, if the donor nucleic acid confers an oncogenic modification;
- (c) a dealing involving a defective viral vector able to transduce human cells in a host mentioned in item 4 of Part 2 of Schedule 2 (animal or human cell culture), unless:
 - (i) the vector is a retroviral vector; or
 - (ii) the donor nucleic acid confers an oncogenic modification.

Schedule 3 Part 2 - Notifiable low risk dealings suitable for physical containment level 2

- (a) a dealing involving whole animals (including non-vertebrates) that:
 - (i) involves genetic modification of the genome of the oocyte or zygote or early embryo by any means to produce a novel whole organism; and
 - (ii) does not involve any of the following:
 - (A) a genetically modified laboratory mouse;
 - (B) a genetically modified laboratory rat;
 - (C) a genetically modified *Caenorhabditis elegans*;
- (aa) a dealing involving a genetically modified laboratory mouse or a genetically modified laboratory rat, if:
 - (i) the genetic modification confers an advantage on the animal; and
 - (ii) the animal is not capable of secreting or producing an infectious agent as a result of the genetic modification;
- (ab) a dealing involving a genetically modified *Caenorhabditis elegans*, if:
 - (i) the genetic modification confers an advantage on the animal; and
 - (ii) the animal is not capable of secreting or producing an infectious agent as a result of the genetic modification;
- (b) a dealing involving a genetically modified plant (including a genetically modified flowering plant), if the dealing occurs in a facility that is designed to prevent the escape from the facility of:
 - (i) pollen, seed, spores or other propagules which may be produced in the course of the dealing; and
 - (ii) invertebrates that are capable of carrying the material mentioned in subparagraph (i);

- (ba) a dealing involving a genetically modified flowering plant, if, before flowering, all inflorescences are wholly enclosed in bags designed to prevent escape of viable pollen and seed;
- (c) a dealing involving a host and vector that are not mentioned as a host/vector system in Part 2 of Schedule 2*, if:
 - (i) the host has not been implicated in, or had a history of causing, disease in human beings, animals, plants or fungi; and
 - (ii) the vector has not been implicated in, or had a history of causing, disease in human beings, animals, plants or fungi;
- (d) a dealing involving a host and vector that are not mentioned as a host/vector system in Part 2 of Schedule 2, if:
 - (i) either:
 - (A) the host has been implicated in, or has a history of causing, disease in human beings, animals, plants or fungi; or
 - (B) the vector has been implicated in, or has a history of causing, disease in human beings, animals, plants or fungi; and
 - (ii) the donor nucleic acid is characterised and is not known to alter the host range or mode of transmission, or increase the virulence, pathogenicity or transmissibility of the host or vector;
- (e) a dealing involving a host/vector system mentioned in Part 2 of Schedule 2, if the donor nucleic acid:
 - (i) encodes a pathogenic determinant; or
 - (ii) is uncharacterised nucleic acid from an organism that has been implicated in, or has a history of causing, disease in human beings, animals, plants or fungi; or
 - (iii) where the vector is able to transduce human cells — confers an oncogenic modification;
- (f) a dealing involving a host/vector system mentioned in Part 2 of Schedule 2 and producing more than 10 litres of GMO culture in each vessel containing the resultant culture, if:
 - (i) the dealing is undertaken in a facility that is certified by the Regulator:
 - (a) as a large scale facility; and
 - (b) to at least physical containment Level 2; and
 - (ii) the donor nucleic acid satisfies the conditions set out in item 4 of Part 1 of Schedule 2;
- (g) a dealing involving complementation of knocked-out genes, if the complementation does not alter the host range or mode of transmission, or increase the virulence, pathogenicity, or transmissibility of the host above that of the parent organism before the genes were knocked-out;
- (h) a dealing involving shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in item 1 of Part 2 of Schedule 2, if the donor nucleic acid is derived from either:
 - (i) a pathogen; or
 - (ii) a toxin-producing organism;

- (i) a dealing involving the introduction of a replication defective retroviral vector able to transduce human cells into a host mentioned in Part 2 of Schedule 2 if the donor nucleic acid is incapable of correcting a defect in the vector leading to production of replication competent virions.

* The Regulations list a number of host/vector systems in Part 2 of Schedule 2 which are those host/vector systems which may be used in exempt dealings.

Dealings are not NLRDs if they are described in Schedule 3 Part 3.